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October 29, 2021

BY E-MAIL

The Honorable Richard Andrews
United States District Court
for the District of Delaware
844 North King Street, Unit 14
Wilmington, DE 19801

VIA ELECTRONIC FILING

Re: *Genentech, Inc., et al v. Apotex Inc.*, et al
C.A. No. 19-78 (RGA) Consolidated

Dear Judge Andrews:

Plaintiffs Genentech, Inc. and InterMune, Inc. (collectively "Plaintiffs") respectfully request leave of Court (1) to amend Plaintiffs' Trial Exhibit List (Exhibit 10 to the Pretrial Order) (D.I. 343) to add a new article published two days ago on October 27, 2021 titled *Effect of early treatment with fluvoxamine on risk of emergency care and hospitalisation among patients with COVID-19: the TOGETHER randomised, platform clinical trial* (Exh. A hereto), and (2) to serve a short supplemental expert report from Plaintiffs' expert Dr. Nathan, to cite the article in further support of previously-disclosed opinions. (Exb. B hereto). Plaintiffs' request is made pursuant to Pretrial Order ¶ 50 [D.I. 343] and Scheduling Order ¶ 12(a), [D.I.19] which require, *inter alia*, that good cause be shown. We have conferred with Defendants' counsel and they oppose this request.

Plaintiffs respectfully submit that good cause exists because of the importance of the article to Plaintiffs' case and it was published only two days ago. The article was published in Lancet Global Health on Wednesday, Oct. 27, 2021 and discloses, *inter alia*, the results of the first large, randomized controlled trial to test the efficacy of fluvoxamine for treatment of COVID-19. These new clinical test results are significant and were widely reported by major news organizations. *See, e.g.*, "Antidepressant Significantly Reduces Covid-19 Hospitalizations," The Wall Street Journal (Oct. 27, 2021)[1].

These clinical findings are supportive of Dr. Nathan's previously disclosed opinions about the results of clinical testing of fluvoxamine as a therapy for treating COVID-19. These opinions

[1] See, e.g., "Antidepressant Significantly Reduces Covid-19 Hospitalizations," The Wall Street Journal (Oct. 27, 2021), available at https://www.wsj.com/articles/antidepressant-significantly-reduces-covid-19-hospitalization-11635373800.

were disclosed at, *inter alia*, paragraph 279 of his May 12, 2021 Supplemental Expert Report, paragraph 63 and footnote 6 of his June 18, 2021 Reply Expert Report, and during his August 13, 2021 deposition, *see* Nathan Dep. Tr. at 39:15-40:4. [Exs. C - E]

There is good cause for Dr. Nathan to serve a short supplemental report addressing this article because (i) it is the largest and most complete study published to date concerning fluvoxamine's clinical testing as a therapy for COVID-19 and (ii) he has already cited three articles concerning earlier clinical testing of fluvoxamine as a COVID-19 treatment: (1) Lenze et al., *Fluvoxamine vs Placebo and Clinical Deterioration in Outpatients With Symptomatic COVID-19*, JAMA, 324(22): 2292-2300 (November 12, 2020) [PTX0315]; (2) Hashimoto, *Repurposing of CNS drugs to treat COVID 19 infection: targeting the sigma 1 receptor*, European Archives of Psychiatry and Clinical Neuroscience (published online January 5, 2021) [PTX0304]; and (3) NIH COVID-19 Treatment Guidelines, last updated April 23, 2021, [PTX0299][2].

Dr. Nathan cites to this research, in part, to rebut arguments made by Defendants' experts suggesting that fluvoxamine purportedly has limited usefulness. This factual issue concerns prospective infringement of certain asserted claims directed to addressing a drug interaction between fluvoxamine and pirfenidone that was discovered by InterMune and patented methods covered by claims it will assert at trial which are directed to patients who need both drugs.

During the parties' meet and confer this afternoon, Defendants asserted that good cause is absent because a preprint of the article was allegedly available in August 2021. Neither Dr. Nathan nor Plaintiffs' counsel were aware of such a preprint, however. Following the meet and confer, Plaintiffs were able to locate a preprint online[3] but note that it contains the following warning—"This article is a preprint and has not been peer-reviewed. It reports new medical research that has yet to be evaluated and so should not be used to guide clinical practice." In contrast, the Oct. 27, 2021 article [Exh. A] is peer-reviewed. Again, Plaintiffs could not have disclosed the peer-reviewed Oct. 27, 2021 article earlier, as it was only published two days ago, and Plaintiffs are providing herewith Dr. Nathan's proposed supplemental report.

Defendants would not be unduly prejudiced by granting the requested leave because the article only further supports Dr. Nathan's previously disclosed opinions, and the parties have time to address it in the week prior to trial.

For all the foregoing reasons, Plaintiffs respectfully submit that good cause exists and hereby request leave to add the new article [Exh A] to Plaintiffs' Trial Exhibit List and for Dr. Nathan to submit a brief supplemental expert report [Exh. B] citing the Oct. 27, 2021 fluvoxamine article in support of his opinions concerning the prospective use of fluvoxamine as a COVID-19 treatment in IPF patients who also need pirfenidone treatment.

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[2] Available at https://www.covid19treatmentguidelines.nih.gov/immunomodulators/fluvoxamine/
[3] Available at https://www.medrxiv.org/content/10.1101/2021.08.19.21262323v1.

Respectfully,

/s/ Karen Jacobs

Karen Jacobs (#2881)

KJ/cpc

cc: Counsel of Record (by CM/ECF and email)